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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,880	09/28/2001	Tasuku Honjo	06501-088001 / J1-101DP2P	4273

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EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/31/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,880

Applicant(s)

HONJO, TASUKU ET AL

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 19-35 and 38-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 9-11, 13-16, 18, 36 and 37 is/are rejected.
- 7) ☒ Claim(s) 1-5, 9-18, 36, and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8, 12, 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Applicant's election with traverse of Invention II, Claims 1-5, 9-18, in part, and 34-37 as well as the species SEQ ID NO: 9 in Paper No. 18 is acknowledged. The traversal is on the ground(s) that no undue burden would be imposed by examination of multiple groups, such as I, II, and X, since searches for these groups would overlap significantly. This is not found persuasive; Groups I, II, and X, are distinct for the reasons described in the prior action. For Groups I, II, and X, each group comprises unique sequences; thus, a search for one group would not encompass a search for any other group and searching all groups would represent a burden on the Office. The requirement is still deemed proper and is therefore made FINAL.

Claims 6-8, 19-35, and 38-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Claims 1-5 and 9-18, in part, and 36 and 37 are examined on their merits.

Those claims limited to subject matter disclosed in JP 11/371,382, SEQ ID NO: 7, nucleotides 1-1832, SEQ ID NO: 8, and SEQ ID NO: 9, are granted the benefit of the priority date December 27, 1999. Claims reciting all of SEQ ID NO: 7 or reciting subject matter first disclosed in PCT/JP00/01918 are not granted the benefit of priority to JP 11/371382.

Claims reciting SEQ ID NO: 7, SEQ ID NO: 9, or SEQ ID NO: 9 are not granted the benefit of priority to Japanese application 11/87192 or 11/178999.

Specification-Objections

The title is objected for the use of the word "novel". All patents are assumed to be novel and said word should be deleted.

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35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be carefully revised in idiomatic English in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear or inexact terms used in the specification are listed below. These examples are in no way exhaustive. Careful editing and correction are required. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

Page 1, line 28: "As the result" should be "As a result".

Page 2, line 7: "phenomena have not yet elucidated" should be "phenomena have not yet been elucidated".

Page 2, line 22: "This namely suggests" should be "This suggests".

Page 49, line 12: "1(b)" should be corrected to "2(b)".

Claims-Objections

Claims 1-5, 9-18, 36, and 37 are objected to for reciting polynucleotides, vectors, and host cells not encompassed by the elected invention. Correction of said claims to recite only the elected invention is required.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 9, 10, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Claim 1 is confusing in that it is not clear whether the “functional fragment” recited is a fragment of the nucleic acid molecule or the protein set forth by SEQ ID NO: 8. In addition, it is not clear what specific function of the “functional fragment” the applicants are intending to recite; for example, enzymatic activity, substrate binding, cofactor binding, immunogenicity and so forth. Since Claims 2, 9, 10, 14, and 15 are dependent from Claim 1, Claims 2, 9, 10, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph for the same reasons. Clarification is required. For purposes of examination, it is assumed that the recited fragments are fragments of SEQ ID NO: 8 and can have any function.

Claims 3, 11, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is confusing and has two interpretations. It is not clear whether Claim 3 is reciting SEQ ID NO: 7 any nucleic acid comprising a fragment of SEQ ID NO: 7 or SEQ ID NO: 7 and any nucleic acid comprising SEQ ID NO: 7. Since, Claims 11 and 16 are dependent on Claim 3, said claims are rejected for the same reasons. Clarification is required. For purposes of examination, it is assumed that Claim 3 is meant to recite SEQ ID NO: an any nucleic acid comprising a fragment of SEQ ID NO: 7.

Claims 5, 13, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is indefinite in the recitation of “hybridizes under stringent conditions” as this term is unclear absent a statement of the conditions under which the hybridization reaction is preformed. Nucleic acids that will hybridize under some hybridization conditions, will not necessarily hybridize under different conditions. The hybridization

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conditions described on page 19, line 5 to page 20, line 2 are only exemplary and do not define the conditions recited in Claim 15. Thus, Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Since, Claims 13 and 18 are dependent on Claim 5, said claims are also rejected for the reasons described for Claim 5.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 36 has two possible interpretations. Claim 36 could be meant to recite a polynucleotide comprising the full-length complement of SEQ ID NO: 9. Alternatively, Claim 36 could be meant to recite a polynucleotide of any length that is complementary to any length of SEQ ID NO: 9. Clarification is required. For purposes of examination, is assumed that Claim 36 is mean to recite a polynucleotide comprising the full-length complement of SEQ ID NO: 9.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 9-11, 13-16, 18, 36, and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotides of SEQ ID NO: 7 and polynucleotides encoding SEQ ID NO: 8, does not reasonably provide enablement for any fragment of the polynucleotide set forth by SEQ ID NO: 7, any fragment of a polynucleotide that hybridizes under stringent conditions to SEQ ID NO: 7, the nucleic acid of SEQ ID NO: 9, any polynucleotide of any length that is complementary to any length of SEQ ID NO: 9, or any polynucleotide that encodes a fragment of SEQ ID NO: 8. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 1 is so broad as to encompass any polynucleotide sequence that encodes a peptide fragment of SEQ ID NO: 8. Claim 2 is so broad as to encompass any polynucleotide sequence that encodes a peptide fragment of a protein that is a peptide fragment of SEQ ID NO: 8. SEQ ID NO: 8. Claim 3 is so broad as to encompass any polynucleotide sequence that is a fragment of SEQ ID NO: 7. Claim 5 is so broad as to encompass any polynucleotide that is a fragment of a polynucleotide that hybridizes under stringent conditions to SEQ ID NO: 7. Claim 36 is so broad as to encompass any nucleic acid comprising a sequence complementary to SEQ ID NO: 9. Claim 37 is so broad as to encompass any polynucleotide of any length that is complementary to any length of SEQ ID NO: 9. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired function requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO 7 and the nucleotide sequence of SEQ ID NO 8.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple fragments, as encompassed by the instant claims, and the positions within a

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protein's sequence where amino acid truncations can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable.

The specification does not support the broad scope of Claim 1, which is so broad as to encompass any polynucleotide sequence that encodes a fragment of SEQ ID NO: 8. The specification does not support the broad scope of Claim 2, which is so broad as to encompass any polynucleotide sequence that encodes a peptide fragment of a protein that is a peptide fragment of SEQ ID NO: 8. SEQ ID NO: 8. The specification does not support the broad scope of the Claims 3 and 5 which, encompasses all polynucleotides that are fragments of SEQ ID NO: 7 or are fragments of any polynucleotide that hybridizes under stringent conditions to SEQ ID NO: 7. The specification does not support the broad scope of Claim 36 which encompasses any nucleic acid comprising a sequence complementary to SEQ ID NO: 9. The specification does not support the broad scope of Claim 37, which encompasses all polynucleotide that are complementary to any length of SEQ ID NO: 9. The specification does not support the broad scope of Claims 1-3, 5, 36, and 37 because the specification does not establish: (A) the activity of any polypeptides that are fragments of SEQ ID NO: 8 or polypeptides encoded by polynucleotides that are fragments of SEQ ID NO: 7, fragments of any polynucleotide that hybridizes to SEQ ID NO: 7, any polynucleotide comprising a sequence complementary to SEQ ID NO: 9, or complementary to any length of SEQ ID NO: 9; (B) regions of any the encoded polypeptides' structures which may be modified without effecting the activity of said polypeptides; (C) the general tolerance of the activity of the polypeptides encoded by the recited polynucleotides to modification and extent of such tolerance; (D) a rational and predictable

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scheme for modifying any residues with an expectation of obtaining the desired biological function; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of polynucleotides corresponding to any fragment of SEQ ID NO: 7, any fragment of a polynucleotide that hybridizes under stringent conditions to SEQ ID NO: 7, comprising a sequence complementary to SEQ ID NO: 9, complementary to any length of SEQ ID NO: 9, or encoding a fragment of SEQ ID NO: 8. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Since Claims 9-11, 13-16, and 18 recite vectors and host cells comprising the polynucleotides of Claims 1-3 and 5, Claims 9-11, 13-16, and 18 are rejected under 35 U.S.C. 112, first paragraph for the same reasons.

Claims 1-3, 5, 9-11, 13-16, 18, 36, and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of nucleic acid molecules with either SEQ ID NO: 7, fragments of SEQ ID NO: 7,

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fragments of any polynucleotide that hybridizes under stringent conditions to SEQ ID NO: 7, polynucleotides comprising a sequence complementary to SEQ ID NO: 9, polynucleotides complementary to any length of SEQ ID NO: 9, or polynucleotides encoding fragments of SEQ ID NO: 8.

The specification does not contain any disclosure of the function of all said nucleic acid molecules. The genus of polynucleotides that comprise these above nucleic acid molecules is a large variable genus with the potentiality of encoding many different proteins with a variety of functions or no function. Therefore, many functionally unrelated polynucleotides and polynucleotides without function are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only two species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Strausberg, 1999 (AI016902) or Strausberg, 1998 (AA954956). Strausberg, 1999 (AI016902) teaches a polynucleotide comprising nucleotides 2211-2652 of SEQ ID NO: 7. Strausberg, 1998 (AA954956) teaches a polynucleotide comprising nucleotides 885-1231 of SEQ ID NO: 7. Furthermore, said polynucleotides inherently encode peptide fragments of SEQ ID NO: 8. Therefore, Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Strausberg, 1999 (AI016902) or Strausberg, 1998 (AA954956).

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Strausberg, 1999 (AW135547). Strausberg, 1999 (AW135547) teaches a polynucleotide comprising nucleotides 832-1231 of SEQ ID NO: 7. Furthermore, said polynucleotide inherently encodes peptide fragment of SEQ ID NO: 8. Therefore, Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Strausberg, 1999 (AW135547).

Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al, 1998 or Adams et al, 1993. Adams et al, 1998 teach a polynucleotide that has 100% identity with SEQ ID NO: 9 over 272 nucleotides, while Adams et al, 1993 teach a polynucleotide that has 100% identity with SEQ ID NO: 9 over 69 nucleotides. Therefore, Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al, 1998 or Adams et al, 1993.

Allowable Subject Matter

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Claims 4, 12, are 17 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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